

Division of Lung Diseases
National Heart, Lung, and Blood Institute, NIH
U.S. Public Health Service, DHHS

SPECIAL INSTRUCTIONS
FOR PREPARATION OF GRANT APPLICATIONS
IN RESPONSE TO RFA: HL-02-013

Specialized Centers of Research (SCOR)

in

- **Neurobiology of Sleep and Sleep Apnea**
- **Airway Biology and Pathogenesis of Cystic Fibrosis**

December 2001

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INSTRUCTIONS FOR THE PREPARATION OF A SCOR GRANT APPLICATION

A. Introduction

These instructions provide information needed for preparation of an application for a Specialized Center of Research (SCOR) in (1) Neurobiology of Sleep and Sleep Apnea or (2) Airway Biology and Pathogenesis of Cystic Fibrosis. They are intended as a companion to RFA: HL-02-013. This RFA appeared in the NIH Guide to Grants and Contracts on December 2001. The application receipt date for this RFA is October 11, 2002.

B. General Information

General instructions for preparation of NIH grant applications are contained in the standard NIH grant application kit (PHS Form 398, revised 5/01, <http://grants.nih.gov/grants/funding/phs398/phs398.pdf>) which is usually available at an applicant institution's business office. Even though the application kit is intended primarily for the regular research-project grant, some of the general instructions and forms in it also apply to SCOR grant applications. However, SCOR grants have special characteristics. Accordingly, the specific instructions in this document were prepared for use with the grant application kit. If questions arise, it is recommended that applicants contact staff of the Division of Lung Diseases. To the extent possible, the Division is prepared to discuss plans for developing an application. Inquiries about preparation of SCOR applications should be addressed to:

Neurobiology of Sleep and Sleep Apnea

Michael Twery, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Two Rockledge Centre, Suite 10018
6701 Rockledge Drive - MSC 7952
Bethesda, Maryland 20892-7952
Telephone: (301) 435-0202
Fax: (301) 480-3557
Email: Twerym@nhlbi.nih.gov

Airway Biology and Pathogenesis of Cystic Fibrosis

Susan Banks-Schlegel, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Two Rockledge Centre, Suite 10018
6701 Rockledge Drive - MSC 7952
Bethesda, Maryland 20892-7952
Telephone: (301) 435-0202
Fax: (301) 480-3557
Email: Schleges@nhlbi.nih.gov

C. Specific Instructions for Specialized Center of Research (SCOR) Applications

1. FACE PAGE (Form Page 1)*

- Type "NHLBI SCOR" in the top left-hand corner of the face page above the words "GRANT APPLICATION." Enter in Item 1 the title SCOR in "(appropriate program area)." In Item 2, check "YES" and insert Number: RFA-HL-02-013 and Title: Specialized Center of Research. In item 3, indicate the name, degree(s), and position (or equivalent) title of the SCOR Director. Complete the rest of the page according to the instructions in the application kit, including the signature of the appropriate institution officials. Be sure to attach the RFA label, found in the application kit, to the bottom of the face page on the original application. Failure to use the RFA label could result in delayed processing of your application, such that it may not reach the review committee in sufficient time for review.

*Refers to appropriate form in the NIH grant application kit (PHS 398, revised 05/01).

2. DESCRIPTION, PERFORMANCE SITES, AND KEY PERSONNEL (Form Page 2)

- Provide a brief description of the proposed SCOR in the space provided. Fill in the performance site(s) and the key professional personnel on this form.

3. RESEARCH GRANT TABLE OF CONTENTS

- Do not use Form Page 3 provided in the application kit. Instead, prepare a table of contents that identifies by page number all major parts of the SCOR so that they can be readily located. When listing individual projects and core(s), identify each by a number, title, and responsible investigator in the order in which they appear in the application. Pages should be numbered sequentially throughout the entire application.

4. DETAILED BUDGET FOR INITIAL BUDGET PERIOD (Form Page 4)

- A detailed budget will be required for **EACH PROJECT AND EACH CORE UNIT** in their respective sections of the application. (See later under Research Plan)
- To aid in the review of your application, it is suggested that you incorporate a detailed budget for all requested support for the first year (Sample Table 1 in the Illustrations). For each category, such as "Personnel," "Equipment," "Travel," and "Other Expenses," give the amount requested for **EACH PROJECT AND CORE UNIT** with subtotals. If contractual arrangements or "purchased services" involving other institutions or organizations are anticipated (as in project 5 and in Sample Table 1 in the Illustrations), include total (direct and indirect) costs associated with such third-party participation in the "Consortium/Contractual Costs" category. In addition, a complete budget for a consortium project is to be developed and identified as such. The published policy governing consortia should be available in the business office of the grantee institution. If clarification is required, the Grants Operations Branch, Division of Extramural Affairs, NHLBI, should be contacted at (301) 435-0171.

5. BUDGET FOR ENTIRE PROPOSED PERIOD (Form Page 5)

- Use Form Page 5 in the application kit to show the total SCOR budget by category requested for each of the 5 years. Justifications for increases in succeeding years should not be included here; they should be delineated in the detailed budget for individual projects.

6. BIOGRAPHICAL SKETCH (Biographical Sketch Format Page)

- Prepare biographical sketches as described in the application kit; they should be placed in alphabetical order immediately after the summary budget information. Biographical sketches are required for all professional personnel participating in the individual SCOR projects and core(s). A form entitled "Biographical Sketch" is provided in the application kit.

INFORMATION (Other Support Format Page)

See the PHS Form 398 Instructions, page 14.

7. RESOURCES

- See section 8.b. below, Institutional Environment and Resources.

8. RESEARCH PLAN

- **Each project should follow the format for the PHS Form 398** and provide supplementary information when necessary for each section as indicated below. Describe each research project and each core unit in the same detail required for an individual research project grant application, so that the scientific merit can be judged on the basis of the written proposal. Keep in mind that the proposal will be reviewed by experts who can judge, collectively, all areas represented in the proposal but who may not be familiar, individually, with each area of research proposed. Therefore, the description of a project should be concise yet explicit enough to enable experts in related areas to understand the main thrust of each project.
- Page limitations specified for individual (R01) grant applications in PHS Form 398 apply to each project and core unit section. Additional information concerning collaboration and integration between projects and cores and the contribution of each component to the program's specific goals should be succinct. It is the responsibility of the principal investigator to ensure that each component is presented as succinctly as possible. Unnecessarily long, wordy, or confusing presentations are usually perceived as indicative of premature or poorly planned research. The bibliography is not counted toward the 25-page limitation per project.

- The following sections should precede the individual projects.
- a. Program Introduction and Statement of Objectives
 - A SCOR should be viewed as a group of interrelated research projects, each of which is not only individually meritorious scientifically but is also complementary to the other projects in the research program and contributes to the integrating theme. The theme of the proposed SCOR should be established in the first few sentences of the general introduction.
 - Describe the rationale for the proposed total research program. Explain the strategy for achieving the objectives of the overall program and how each research project and core unit relates to that strategy.
 - The general introduction of the overall program description is the appropriate place to indicate any prior collaborative arrangements between investigators in the group, to emphasize the events that have led to the current application, to anticipated unique advantages that would be gained by the research within the proposed SCOR, to describe how the projects are synergistic and mutually reinforcing, and to explain how the projects collectively would enhance the stated objective of the proposed research.
 - b. Institutional Environment and Resources
 - Briefly describe the features of the institutional environment that are relevant to the effective implementation of the overall program. As appropriate, describe available resources such as clinical and laboratory facilities, participating and affiliated units, patient populations, geographic distribution of space and personnel, and consultative resources. The information requested here supplants the “Resources” page in the PHS Form 398 grant application, which is NOT to be used in describing the overall SCOR program.
 - c. Organizational and Administrative Structure of a SCOR
 - Describe in detail, and by diagram, if appropriate, the chain of responsibility for decision-making and administration, beginning at the level of SCOR Director and including investigators responsible for the direction of the research projects and core units. The Director of the overall SCOR is called the principal investigator; the leaders of the individual projects in a SCOR are project leaders. Indicate where, in the chain of responsibility, advisory groups (internal and external consultants) would be used.
 - Advisory groups: Provide a description of the function of advisory groups (internal and external) used to provide advice and quality control. Identify the expertise needed but do not identify by name the external consultants serving on the advisory groups.
 - Specific managerial responsibilities: Indicate who would be responsible for assisting the SCOR Director with the day-to-day administrative details, program coordination, and the planning and evaluation of the program.

- Relation of the SCOR organization to the administration of the applicant institution: Describe the relation between the proposed SCOR and other existing research, academic, and administrative units of the applicant institution such as schools, centers, institutions, departments, and central administration.
- Consortium arrangements: If a SCOR application includes research activities that involve institutions other than the sponsoring organization, the program is considered a consortium effort. Such activities may be included in a SCOR grant application, but it is imperative that a consortium application be prepared so that the programmatic, fiscal, and administrative considerations are explained fully. The published policy governing consortia is available in the business offices of institutions that are eligible to receive Federal grants-in-aid. Consult the latest published policy governing consortia before developing the application. If clarification of the policy is needed, contact the Grants Operations Branch, Division of Extramural Affairs, NHLBI, at 301-435-0171. Principal Investigators of SCORs should exercise great diligence in preserving the interactions of the participants and the integration of the consortium projects with those of the parent institution.
- Designation of replacement for SCOR DIRECTOR: Describe the procedure for appointing a replacement for the SCOR Director, should the need arise. The NHLBI must approve the replacement of the SCOR Director.

d. Summary Report of Progress

- Competing continuation applications must include a progress report that highlights achievements under the SCOR since the last competitive review. A progress report is required for each research project and core unit in other sections of the application. This composite summary-progress report must include the following information:
 - 1) A brief summary of major accomplishments that can be attributed to the SCOR grant and a brief explanation of how these accomplishments have contributed to furthering the stated objectives of the program.
 - 2) A list of all publications and completed (not “in preparation”) manuscripts that have resulted from the SCOR grant.
 - 3) A list of changes, if any, in the professional staffing since the last competitive review.
 - 4) A list of research projects and core units, in tabular form, that have been discontinued, modified, or completed since the last competitive review, identified by number and title, with a brief explanation of the actions taken.
 - 5) A list of research projects and core units in the current program, with the amount of current funding for each and the requested funding for the first budget period of each project and core unit that would be continued in the SCOR. Identify each as a “new” or “continuing” component.

■ Individual Projects

1. Title and number each research project so that it can be readily distinguished from any other project in the program. An individual ABSTRACT should be prepared for each project in the SCOR as would be required for an R01 (Individual Research Grant). The title must NOT exceed 56 typewriter characters/spaces. DO NOT provide a face page (i.e., PHS Form 398 face page) for individual projects. Provide the name, and academic title of the project leader and each participating investigator.
2. The budget for each research project must be presented according to the instructions indicated for PHS Form 398. A detailed budget is required for the first and all subsequent years. Include budget requests and explicit detailed budget justifications for all years.
3. Research Plan: State the overall objective of the proposed research and explain the relation of the research project to the central theme of the SCOR and how the project relates to, and both complements and supplements, the other research projects and core units in the program.
 - a. Specific Aims
 - List the specific aims of the research project for the total period of requested support. Indicate the general priority of each aim in the overall research plan.
 - b. Background and Significance
 - Review the most relevant previous work and describe the current status of research in this field; document with complete references. Specify the overall biomedical significance of the work proposed and the relevance of the research project to the theme of the SCOR.
 - c. Preliminary Studies/Progress Report
 - Refer to PHS Form 398 Instructions for Preliminary Studies.
 - See under Progress Report for Competing Continuation Applications.
 - d. Research Design and Methods
 - Give details of the research plan, including a description of the experiment or other work proposed; present the methods and techniques to be used; note the limitations, if any, of the procedures proposed. Insofar as possible, describe the experiments in the sequence in which they would be conducted. (It is important to convey to the reader that the proposed effort would require the time requested for the project period.)

e. Human Subjects

- The NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear and compelling rationale should be provided. The policy can be found in the NIH Guide for Grants and Contracts of March 18, 1994, Volume 23, Number 11 and available on the web at: <http://grants.nih.gov/grants/guide/notice-files/NOT-0D-00-048.html>.
- The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design sample size appropriate for the scientific objectives of the study. This information should be included in PHS Form 398 in section 9, a-d of the Research Plan AND summarized in section 9, e, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, the NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of U.S. racial/ethnic minority populations (i.e., Native Americans including American Indians or Alaska Natives, Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.
- It is the policy of the NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998. All investigators proposing research involving human subjects should read the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>
- For the purpose of grant applications, this policy includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders, or conditions.
- The usual NIH policies concerning research on human subjects also apply. Form 398 should be followed for human subjects information.
- For foreign components, the policy on inclusion of women and children applies fully. Because the definition of minority differs in other countries, the applicant

must discuss the relevance of research involving foreign population groups to the U.S. populations, including minorities.

- If the required information is not contained within the application, the application will be returned.
 - Include a Data and Safety Monitoring Plan in the application that describes the organizational structures and procedures that will be employed to ensure the safety of participants and validity and integrity of the data according to NIH policy that can be found at <http://grants,bug,giv/grants/guide/notice-files/not98-084.html>
- f. Vertebrate Animals (see PHS Form 398 Instructions)
- If animals are involved, indicate what kinds are to be used and whether nonhuman primates are to be used, listing the special justifications for their use, and indicate all details for the care, use, treatment, and dispatch of all animals.
- g. Literature Cited
- Include a complete citation for each reference in the text. TITLES OF REFERENCE PUBLICATIONS SHOULD BE INCLUDED.
- h. Consortium/Contractual Arrangements and/or Collaborative Arrangements (See PHS Form 398 Instructions)
- Describe the collaboration of investigators within the SCOR. Describe in detail any other collaborative arrangements anticipated, either within the applicant institution or between institutions.
- i. Consultants (see PHS Form 398 Instructions)
- Provide a justification for consultants and attach letters from all individuals confirming their roles in the project.
- k. Facilities Available
- Describe the facilities to be used by EACH research project. This is to be accomplished as described under "Resources," in PHS Form 398 grant application, page 15.
9. APPENDIX
- Appendix material should NOT be included as part of the grant application. Once the application has been received, the Scientific Review Administrator will send the applicant instructions for submitting appendix material. This material includes reprints pertinent to each project or core, and color or half-tone figures. The reviewers will not receive an original copy of the grant application so the appendix should include either originals of the pages or full size copies of any figures where

color or clarity is critical to the review. As the PHS Form 398 instructions indicate, the appendix should not be used to circumvent the page limitations.

FORMAT OF A CORE UNIT

- A core unit is defined as a resource for the program project that provides centralized services to two or more of the research projects.
- a. Title of core unit
- Title and assign a LETTER designation to each core so that it can be readily distinguished from any other core unit. Do NOT exceed 56 typewriter characters/spaces for its title.
- b. Names and titles of investigators
- Provide the name and academic title of the core unit leader and each participating investigator.
- c. Description of core unit
- Describe the function of the core unit as a resource to the SCOR. This section must present clearly the facilities, techniques, and professional skills that the core unit would provide. As justification for the core unit, indicate briefly the specific research projects that would use the resources of the core unit. A core unit is principally designed as a service or resource component; it would be highly unusual to include research in a core unit (a possible exception would be methodology development). Please contact the Institute staff if you require guidance on this issue.
- d. Facilities available
- Describe the facilities to be used by EACH core unit. This is to be accomplished by completing the "Resources" page included in the PHS Form 398 grant application, page 15.
- e. Budget for core unit
- Present the budget for each core unit in the format and according to the instructions indicated for Form 398. A budget for the entire proposed project period is required for all subsequent years of support (direct costs only). Include explicit and detailed budget justifications for all years.
- f. Relation of core units to research projects
- To aid in the review of your application it is recommended that you prepare in tabular form information concerning the research projects that each core unit would serve and

the proportion of the cost of the core unit associated with each research project involved, according to the format presented in Sample Table 2 in the Illustrations. While Sample Table 1 is to be found in all Form PHS 398 applications (Form Page 4), Sample Table 2 is suggested for use (in tabular form) to help the reviewers in the evaluation of a SCOR grant application.

TABLE 1

Detailed Budget for Initial Budget Period
Direct Costs Only

| | | From | Through | | |
|--|-------------------|-----------------|--------------------------------------|-----------------|-----------|
| Personnel (Applicant organization only) | | Time/Effort | Dollar Amount Requested (Omit cents) | | |
| Name | Title of Position | %Hours per Week | Salary | Fringe Benefits | Totals |
| Project 1 | | | \$30,000 | \$3,000 | \$33,000 |
| Project 2 | | | 20,000 | 2,000 | 22,000 |
| Project 3 | | | 25,000 | 2,500 | 27,500 |
| Project 4 | | | 15,000 | 1,500 | 16,500 |
| Core Unit A | | | 22,000 | 2,200 | 24,200 |
| Core Unit B | | | 10,000 | 1,000 | 11,000 |
| Subtotals | | | 122,000 | 12,200 | 134,200 |
| Consultant Costs (See instructions) | | | | | |
| Project 2 (\$1,000), Core Unit A (\$2,000) | | | | | 3,000 |
| Equipment (Itemize) | | | | | |
| Project 1 (\$4,000), Project 2 (\$2,000), Project 3 (\$3,000), Project 4 (\$5,000), Core Unit A (\$16,500), Core Unit B (\$2,000) | | | | | 32,500 |
| Supplies (Itemize by project/core) | | | | | |
| Project 1 (\$14,200), Project 2 (\$2,000), Project 3 (\$11,500), Project 4 (\$8,900), Core Unit A. (\$16,400), Core Unit B (\$18,200) | | | | | 79,900 |
| Travel | Domestic | | | | 3,000 |
| | Foreign | | | | 1,000 |
| Patient Care Costs | Inpatient | Project 4 | | | 20,000 |
| | Outpatient | | | | |
| Alterations and Renovations (Itemize by project/core) | | | | | |
| Other Expenses (Itemize by project/core) | | | | | |
| Project 1 (\$1,000), Project 2 (\$1,500), Project 3 (\$1,900) Project 4 (\$1,100), Core Unit A (\$1,500), Core Unit B (\$2,200) | | | | | 9,200 |
| Subtotal Direct Costs For Initial Budget Period | | | | | 279,800 |
| Consortium/Contractual Costs (See instructions) | | | | | |
| Project 5 - Collaborating Institution (\$45,200 DC, plus \$10,000 F&A Costs) | | | | | 55,200 |
| Total Direct Costs (Also enter on Page 1, item 7) | | | | | \$335,000 |

TABLE 2**Relation of Core Units to Research Projects**

| <u>Projects</u> | <u>Core Unit A</u> | <u>Core Unit B</u> |
|-----------------|--------------------|--------------------|
| Project 1 | \$ 3,000 | \$ 6,900 |
| Project 2 | 13,100 | 6,000 |
| Project 3 | 14,500 | 10,000 |
| Project 4 | 10,000 | 6,000 |
| Project 5 | 20,000 | 4,500 |
| Totals | \$ 60,600 | \$ 33,400 |